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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/772,374	02/06/2004	Benjamin Gaston	28195-503 CON	6783
20306	7590	01/31/2006	EXAMINER	
MCDONNELL BOEHNEN HULBERT & BERGHOFF LLP			HENLEY III, RAYMOND J	
300 S. WACKER DRIVE			ART UNIT	
32ND FLOOR			PAPER NUMBER	
CHICAGO, IL 60606			1614	

DATE MAILED: 01/31/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	<b>Application No.</b> 10/772,374	<b>Applicant(s)</b> GASTON ET AL	
	<b>Examiner</b> Raymond J. Henley III	<b>Art Unit</b> 1614	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

#### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) ☒ Responsive to communication(s) filed on 3.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) ☒ Claim(s) 1 and 9 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1 and 9 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)   | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                                   | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)             |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____  |

**CLAIMS 1 AND 9 ARE PRESENTED FOR EXAMINATION**

Applicants' amendment filed November 3, 2005 has been received and entered into the application. Accordingly, the specification at page 1 and claim 9 have been amended.

In view of the above amendments, the objection to the specification and claim 9, as set forth in the previous Office action dated August 1, 2005, are withdrawn.

***Comments Concerning the Prosecution of the Parent Application***

In the previous Office action at pages 5-7, the Examiner stated that the present application, which is a "stand-alone" continuation application, i.e., as compared to an RCE application, must be as complete as possible. It was further stated that the present record is unclear with respect to the issue of obviousness under 35 U.S.C. § 103 over, *inter alia*, Garvey et al. (U.S. Patent No. 6,331,543) in view of Stamler (U.S. Patent No. 6,314,956) which issue was raised in the parent application, i.e., Serial No. 10/380,763, ("the '763 application"), (see the Office action dated August 21, 2003 in the '763 application), and which was not raised during the prosecution of the present application.

In Applicants' above referenced response, Applicants stated that they believed that the issue under 35 U.S.C. § 103, as set forth in the previous Application, has been overcome based upon the papers filed in the parent application. Upon reconsideration, the Examiner cannot agree because each application must be complete and this includes both Applicants and the Office's position regarding art cited in the parent application that would apply to the claims in the present application. This is not the case here where the Examiner's rejection under 35 U.S.C. § 103 and

Art Unit: 1614

Applicants arguments/declarations set forth in the parent application have not been made of record in the present application.

The Examiner merely explained this rejection and why, if submitted, the papers of the parent application would overcome the presumption of obviousness as set forth in previous Office action. The Examiner failed to, however, formally make the rejection. The Examiner apologizes for this oversight. A proper rejection under 35 U.S.C. § 103 follows. Applicants' cannot rely on arguments/declarations presented in the parent application because such arguments/declarations have not been made of record herein.

***Claim Rejection - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 1 and 9 are rejected under 35 U.S.C. 103(a) as being unpatentable over Garvey et al., (U.S. Patent No. 6,331,543) in view of Stamler (U.S. Patent No. 6,314,956).

Art Unit: 1614

Claim 1 of the present application is representative of the subject matter claimed by Applicants and reads:

1. (Previously presented) A method for treating cystic fibrosis, said method comprising the step of administering a therapeutically effective amount of a composition comprising an S-nitrosothiol to a patient having cystic fibrosis, wherein the composition is formulated as a powder or an aerosol and administered to the nasal mucosa and osteomeatal complex.

The other pending claim, claim 9, is substantially the same as claim 1, but requires the administration of ethyl nitrate, which is not an S-nitrosothiol compound as in present claim 1.

Garvey et al., (U.S. Patent No. 6,331,543), is directed to the use of certain nitrosated and/or nitrosylated phosphodiesterase inhibitors, (not compounds of the present invention), and optionally one or more compounds that donate, transfer or release nitric oxide (which would encompass the compounds of the present invention), (see, for example, the abstract). Garvey et al. teaches that the above inhibitors and compounds may be used for treating diseases induced by the increased metabolism of cyclic guanosine 3', 5'-monophosphate (cGMP). The treatment of cystic fibrosis is disclosed as such a disease (see col. 4, line 67). S-nitrosothiols are also disclosed (col. 53, line 62 – col. 54, line 67). Garvey et al. also teach that the compositions may be administered by inhalation spray (col. 58, lines 17-20).

The differences between the subject matter of the present claims and that taught by Garvey et al. lie in that Garvey et al. fail to highlight ethyl nitrite, (present claim 9) and the nasal/osteomeatal complex administration of present claims 1 and 9.

However, to the skilled artisan, the claimed subject matter would have been obvious because at column 53, line 52, Garvey et al. teach that organic nitrites may be employed and

Art Unit: 1614

thus would have included ethyl nitrite, a known organic nitrite. Also, the general formula in Garvey et al. at column 55, lines 28-31 would have encompassed ethyl nitrite.

Additionally, because Garvey et al. teach inhalation spray in general (col. 58, line 20), such would have included known routes of inhalation which included the mouth as well as the nose. Stamler et al. is included to show that inhalation of a nebulized nitric oxide donor where the donor is present as solid or liquid particles was known. The selection of the means for delivering the medicament from those known would have been a matter well within the purview of the skilled artisan.

Accordingly, the claims are deemed properly rejected.

### ***Double Patenting***

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 1 and 9 remain rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1, 2, 14 and 15 of U.S. Patent No. 6,627,602. Although the conflicting claims are not identical, they are not patentably distinct from each other because of the reasons set forth in the previous Office action dated August 1, 2005 at pages 3-5.

Art Unit: 1614

Applicants have indicated that this rejection will be disposed of after all other issues are resolved.


Insofar as a proper terminal disclaimer has not been filed, the rejection is deemed to remain proper.

None of the claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Raymond J. Henley III whose telephone number is 571-272-0575. The examiner can normally be reached on M-F, 8:30 am to 4:00 pm Eastern Time.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christopher Low can be reached on 571-272-0951. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

  
Raymond J Henley III  
Primary Examiner  
Art Unit 1614

January 27, 2006